

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re Application of: MESSERLI et al.

Application No.: 09/497,123

Group Art Unit: 3738

Filed: February 3, 2000

Examiner: Brian E. Pellegrino

For: END MEMBER FOR A
BONE FUSION IMPLANT

Attorney Docket No.: 8932-114

BRIEF ON APPEAL FEE TRANSMITTAL

Assistant Commissioner for Patents
Washington, D.C. 20231

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JUL 30 2002

Sir:

TECHNOLOGY CENTER R3700

An original and two copies of the applicant's Brief on Appeal in the above-entitled application are submitted herewith. The item(s) checked below apply:

- The Brief filing fee is \$320.00.
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The Brief filing fee is:

- Required.
- Not required (Fee paid in prior appeal).

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Date

July 26, 2002

Respectfully submitted,

Brian M. Poissant

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DS
~~HIS~~

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In re Application of: D. Messerli et al.

Application No.: 09/497,123

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Sir:

This appeal is taken from the Final Rejection dated October 26, 2001, in which claims 1, 2, 7, 9, 14, 15, and 17-19 were finally rejected.

Real Party In Interest - 37 C.F.R. § 192(c)(1)

The real party in interest is Synthes (USA), a General Partnership having a place of business at 1690 Russell Road, Paoli, Pennsylvania 19301, to which the present application has been assigned by the applicants.

Related Appeals and Interferences - 37 C.F.R. § 1.192(c)(2)

There are no related appeals or interferences which will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

Status of Claims - 37 C.F.R. § 1.192(c)(3)

Claims 1, 2, 7, 9, 14, 15, and 17-19 are appealed. Claims 1, 7, 9, 14, 15, and 17 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,702,451 to Biedermann *et al.* (the "Biedermann '451 patent"). Claims 1, 2, 9, and 14 were rejected

under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent No. 5,776,197 to Rabbe *et al.* (the “Rabbe ‘197 patent”). Claims 1, 2, 17, and 18 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,700,291 to Kuslich *et al.* (the “Kuslich ‘291 patent”) in view of U.S. Patent No. 6,143,033 to Paul *et al.* (the “Paul ‘033 patent”). Claim 19 was rejected under 35 U.S.C. § 103(a) as being unpatentable over the Kuslich ‘291 patent in view of the Paul ‘033 patent and further in view of U.S. Patent No. 6,086,613 to Camino *et al.* (the “Camino ‘613 patent”)

Claims 3, 5, 6, 8, 10-13, 16, 20, 21, and 24 have been canceled and claims 4, 22 and 23 have been withdrawn from consideration, as being drawn to non-elected species.

No claim has been allowed.

Status of Amendments - 37 C.F.R. § 1.192(c)(4)

An amendment, amending claim 1 as shown in attached Appendix A, was filed on January 28, 2002 subsequent to final rejection, and it was denied entry. During a personal interview conducted with the Examiner on January 30, 2002, amended claim 1 was discussed and the Examiner indicated that the amendment “appears” to overcome the Biederman reference, but “requires further review of the Rabbe reference.” However, in an advisory action mailed February 28, 2002, the Examiner denied entry of the amendment because the amendment “requires further consideration and a search.”

Summary of the Invention - 37 C.F.R. § 1.192(c)(5)

The present invention is drawn to an end member for use with a bone fusion implant for fusing portions of bone. Bone fusion implants are utilized in orthopaedic surgery for the treatment and management of bone defects and injuries. Fusion implants can be used to restore natural anatomical length and shape of long bones with a bone defect. These implants can also be inserted as a vertebral spacer whenever a disc, vertebra or combination of disc and vertebra have to be removed to restore the natural length and curvature of the spine as well as to promote bone fusion. Restoring spinal anatomy and stability and promoting bone fusion are even more difficult in a corpectomy, a surgical procedure in which a section of one or several vertebrae is removed.

Many different implants have been developed for use with bone defects. So-called "mesh implants" have shown to be effective. One such implant is the SynMesh™ available from Synthes (USA) of Paoli, Pennsylvania. The SynMesh™ is a titanium mesh cylinder which is provided with a plurality of apertures along its side wall. In order to address the different clinical situations in which bone defects arise, the SynMesh™ is available in a variety of lengths, shapes, and diameters. Also, commercially available allografts for treating bone defects have recently become available.

Although the clinical results of mesh and allograft implants have generally been positive, one possible clinical complication is subsidence of the implant. Excessive sinking of the ends of the implant into the bone with which they contact is especially troublesome. From both a mechanical and physiological point-of-view, it would be advantageous to increase the surface contact area between the implant and bone by providing an end plate. U.S. Patent No. 5,702,451 to Biedermann et al. discloses end rings that attempt to address these concerns. However, the end rings disclosed have no provisions for holding, insertion, and distraction instruments. Thus, implantation during surgery can be particularly difficult and time consuming.

It would be advantageous to provide a channel extending from the edge of the top surface of the end plate to receive a surgical instrument to facilitate the holding and insertion of the device in operation. For example, one suitable instrument is described in U.S. Patent No. 6,261,296 to Aebi *et al.*, which is owned by the assignee of the present application. Accommodation of such a surgical instrument is particularly desirable since the implant can be more readily inserted into a relatively smaller incision. In accordance with one embodiment the present invention, the end member has a first portion, a second portion sized to be inserted into the bore of the implant, and a shoulder between the first and second portions. When the second portion is inserted into the bore, the shoulder rests on an edge of the implant. The top surface of the first portion conforms in size and shape with the bone and has a channel or multiple channels for receiving a surgical instrument. When multiple channels are present, all the channels can run in the same direction, (e.g. the channels run in the anterolateral direction), or the channels can run in different directions, (e.g. a first channel runs in the anterior-posterior direction and a second channel runs in the lateral direction).

Issues on Appeal - 37 C.F.R. § 1.192(c)(6)

(1) Whether claims 1, 7, 9, 14, 15, and 17 are anticipated, within the meaning of 35 U.S.C. § 102(b), by the Biedermann '451 patent.

(2) Whether claims 1, 2, 9, and 14 are anticipated, within the meaning of 35 U.S.C. § 102(e), by the Rabbe '197 patent.

(3) Whether claims 1, 2, 17, and 18 are obvious, within the meaning of 35 U.S.C. § 103, based on the teachings of the Kuslich '291 patent in view of the Paul '033 patent, and whether claim 19 is obvious in view of the Kuslich '291 patent in combination with the Paul '033 patent and the Camino '613 patent.

Grouping of Claims - 37 C.F.R. § 1.192(c)(7)

For purposes of this appeal, the claims are grouped as follows:

Claims 1, 7, 9, 14, 15, 17, and 19 stand or fall together;

Claim 2 stands alone; and

Claim 18 stands alone.

Appellants' Argument - 37 C.F.R. § 1.192(c)(8)

I. The Biedermann '451 Patent Does Not Disclose, Teach or Suggest a First Channel Extending From the Edge for Receiving a Surgical Instrument.

What the Examiner has cited as being a "channel" in the Biedermann '451 patent, *i.e.*, holes 14 or the spaces between prongs 21, is in fact not a "first channel extending from the edge for receiving a surgical instrument," as presently claimed.

A. Holes 14

The Examiner asserts that holes 14 can be construed as a channel. Applicants respectfully disagree. As shown and described in the instant application, the claimed channel is a longitudinal groove for receiving a surgical instrument. The applicable dictionary definition of "channel" is a furrow, trench, or groove. The American Heritage College Dictionary (3rd Ed.). The holes 14 the Biedermann '451 patent are circular in shape and are located on the interior of the plate, spaced a distance from the edge of the top surface, and extend longitudinally through the plate, not across the top surface. In contrast, the end

member according to claim 1 has a top surface ... having an edge and a first channel extending from the edge of the top surface for receiving a surgical instrument. Moreover, the Biedermann '451 patent does not teach, suggest, or disclose that holes 14 are for receiving a surgical instrument but to the contrary are provided for the purpose of allowing bone ingrowth.

B. The Space Between Prongs 21

The Examiner also asserts that prongs 21 have channels established anterollaterally between the prongs. In support, the Examiner has provided Attachment A showing Figure 9 of the Biedermann '451 patent with "top of prongs" labeled. Applicants respectfully disagree with this characterization. The Biedermann '451 patent states that "FIG. 8 shows a section along line VIII-VIII in FIG. 9." As Figure 8 clearly shows that the prongs do not extend above ring 12 and are not located on a top surface adopted and configured to engage bone, there is no channel on the top surface as recited in claim 1. Additionally, the prongs 21 are inserted into recesses 9, 10, 9', 10' of jacket 1 so that any space between the prongs is contained within the jacket and cannot be used to receive a surgical instrument.

Thus, the "holes 14" or the "space between prongs 21" cannot be construed as "a first channel" in the top surface "extending from the edge for receiving a surgical instrument," as that phrase is recited in claim 1. As a result, independent claim 1, and claims 7, 9, 14, 15, and 17 dependent thereon are not anticipated by the Biedermann '451 patent and, therefore, applicants respectfully request the Board to reverse the rejection of these claims under 35 U.S.C. § 102.

II. The Rabbe '197 Patent Does Not Disclose, Teach or Suggest an End Member with "a Shoulder Sized to Rest on an Edge of the Implant When the Second Portion Is Inserted in the Bore of the Implant."

What the Examiner cites as being a "shoulder" in the Rabbe '197 patent, *i.e.* first portion 35, is in fact not "a shoulder sized to rest on an edge of the implant when the second portion is inserted in the bore of the implant," as recited in independent claims 1 and 2.

A. Claims 1, 2, 9, and 14

The Examiner asserts that Fig. 3 of the Rabbe '197 patent shows an end member 22 with a first portion 35 and a second portion 37, and "the first portion 35 can be interpreted as a shoulder since it extends beyond the second portion." However, member 22 identified by the Examiner in the Rabbe '197 patent has an annular surface with internal threading that goes *outside* of the threaded cylindrical body 21. (*See* Fig. 3). In this configuration, it is clear that element 35, which the Examiner alleges to be a shoulder, is not *sized to rest on an edge of the implant*, as flange 35 never contacts body 21. In fact, since the second portion of the Rabbe '197 patent goes outside of body 21, the alleged shoulder must necessarily be sized larger than body 21, not *sized to rest on an edge* thereof.

In addition, the Rabbe '197 patent does not disclose, teach, or suggest a "first channel" in the top surface "extending from the edge for receiving a surgical instrument," as recited in claims 1 and 2. Instead, the mounting slots 47 disclosed in the Rabbe '197 patent are configured to support a separate end cap 23. (*See e.g.* col. 6, lines 52-54). Moreover, end cap 23 is configured to be held in position, *i.e.* covering mounting slots 47, "particularly when the replacement body is disposed between the adjacent intact vertebrae V₂ and V₄." (Col. 6, lines 61-65). In this manner, end cap 23 actually prevents a surgical instrument from being received in slots 47. Thus, for this additional reason, the Rabbe '197 patent does not anticipate independent claims 1 and 2 of the present application.

B. Claim 2

In addition, claim 2 recites that the teeth are provided in a two dimensional array with the teeth being spaced apart from one another for interlocking with the bone. As teeth 91 in the Rabbe '197 patent form a single ring and not a two dimensional array, Applicants submit that claim 2 is patentable over this reference for this additional reason.

Thus, the Rabbe '197 patent does not anticipate independent claim 2 and, therefore, applicants respectfully request the Board to reverse the rejection of claims 1, 2, 9, and 14 under 35 U.S.C. § 102.

III. The Paul '033 Patent Is Disqualified as Prior Art Because That Subject Matter Was Owned by The Same Person at The Time The Invention Was Made

Pursuant to 35 U.S.C. § 103(c) and M.P.E.P. § 706.02(l)(1), effective November 29, 1999, subject matter which was prior art under former 35 U.S.C. §103 via 35 U.S.C. § 102(e) is now disqualified as prior art against the claimed invention if that subject matter and the claimed invention "were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person." Common ownership of the Paul '033 patent and the rights to the present application may be found in the assignment documents which are recorded in the Patent and Trademark Office at Reel 9818, Frame 0557 for the Paul '033 patent and at Reel 010597, Frame 0246 for the present application, conveying the entire rights in the applications to "Synthes (U.S.A.)" of Paoli, PA, the same organization. Accordingly, the Paul '033 patent is disqualified as prior art against the presently claimed invention.

Since the Paul '033 patent does not qualify as prior art, applicants respectfully submit that the teachings of the Kuslich '291 patent in combination with the Camino '613 patent does not achieve the invention of the present application. Thus, the cited art does not render claims 1, 2, 17, 18 and 19 of the present invention obvious and, therefore, applicants respectfully request the Board to reverse the rejection of claims 1, 2, 17, 18, and 19 under 35 U.S.C. § 103.

In summary, the cited references do not disclose, teach, or fairly suggest the invention as presently claimed.. Reversal of the Examiner and allowance of all the claims are accordingly respectfully requested.

Respectfully submitted,



Date July 26, 2002

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Enclosures

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APPENDIX A

Amended Claim 1 (Submitted January 28, 2002)

1. An end member for use with an implant for fusing bone comprising:
a first portion with a top surface adopted and configured to engage the bone and
having a[n] perimeter edge and a first channel extending across at least a portion of the top
surface from the perimeter edge for receiving a surgical instrument;
a second portion configured and dimensioned to be inserted into a bore of the implant;
and
a shoulder joining the first and second portions and sized to rest on an end edge of the
implant when the second portion is inserted in the bore of the implant.

APPENDIX B

Claims on Appeal - 37 C.F.R. § 1.192(c)(9)

1. An end member for use with an implant for fusing bone comprising:
 - a first portion with a top surface adopted and configured to engage the bone and having an edge and a first channel extending from the edge for receiving a surgical instrument;
 - a second portion configured and dimensioned to be inserted into a bore of the implant; and
 - a shoulder joining the first and second portions and sized to rest on an edge of the implant when the second portion is inserted in the bore of the implant.
2. An end member for use with an implant for fusing bone comprising:
 - a first portion with a top surface adopted and configured to engage the bone and having an edge and a first channel extending from the edge for receiving a surgical instrument;
 - a second portion configured and dimensioned to be inserted into a bore of the implant; and
 - a shoulder joining the first and second portions and sized to rest on an edge of the implant when the second portion is inserted in the bore of the implant,
wherein the top surface further comprises a plurality of teeth provided in a two dimensional array with the teeth being spaced apart from one another for interlocking with the bone.
7. The end member of claim 1 wherein the top surface is oval.
9. The end member of claim 1 wherein the top surface is a flat planar surface.
14. The end member of claim 1 wherein the top surface has a second channel for receiving a surgical instrument.

15. The end member of claim 14 wherein the first and second channels run in an anterolateral direction.

17. The end member of claim 1 wherein the second portion comprises a plurality of tabs to secure the end member to the implant.

18. The end member of claim 17 wherein each of the plurality of tabs is resilient, flexing inward upon insertion of the second portion in the implant and flexing back outward to secure the end member to the implant.

19. The end member of claim 1 wherein the end member is made of a metal.



FIG. 8

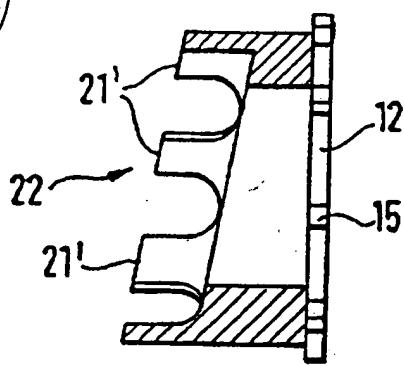


FIG. 9

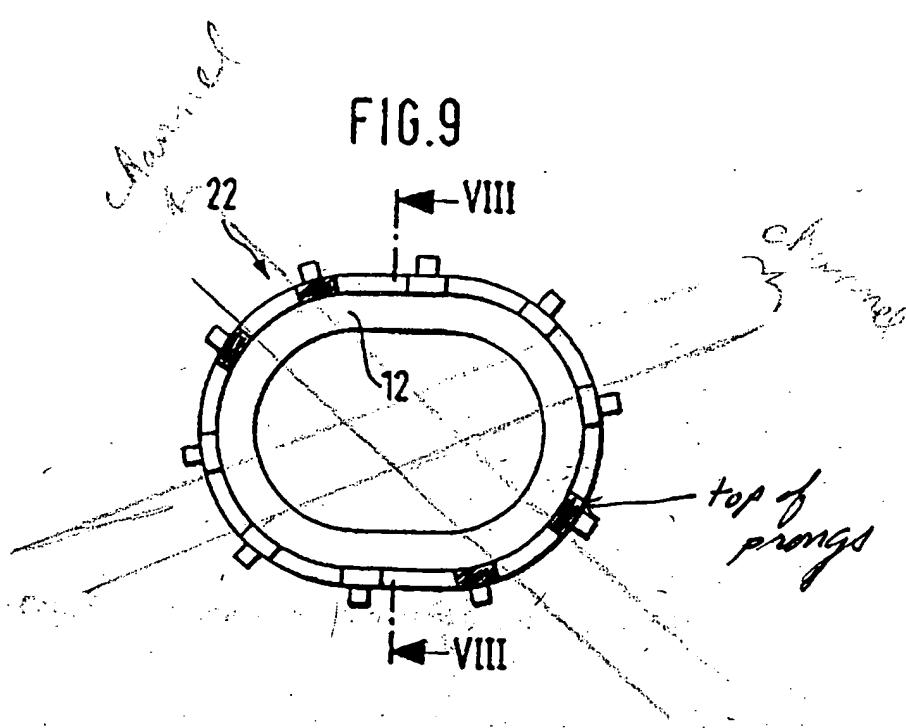


FIG. 10

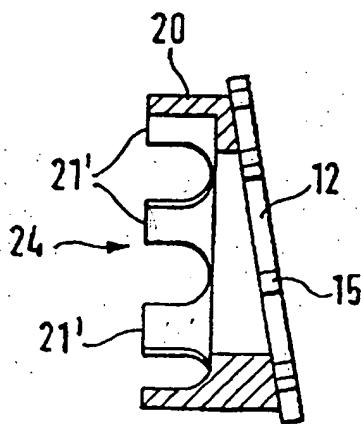


FIG. 11

